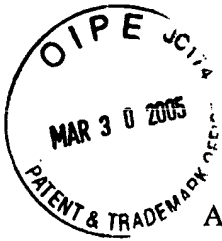


MILBANK, TWEED, HADLEY & MCCLOY LLP

SERIAL NO. 10/603,129  
ATTORNEY DOCKET NO. 33915-03420



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David J. Schuessler Art Unit: 1772  
Serial No.: 10/603,129 Examiner: Sandra M. Nolan  
Filed: June 24, 2003

Based On:  
Serial No.: 09/908,414  
Filed: July 18, 2001

Title: ROTATIONALLY MOLDED MEDICAL ARTICLES

**37 C.F.R. 1.131 Declaration of David Schuessler**

I, David Schuessler state under penalty of perjury that, to the best of my knowledge and belief, the following is true and correct:

1. I am employed by Inamed, Inc., and have the title of Senior Project Manager. I submit this affidavit in support of Response F to the U.S.P.T.O.'s Office Action dated September 30, 2004.

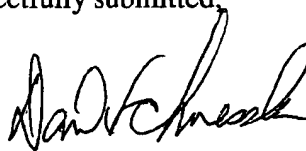
2. I am the sole inventor for the above-titled application. I have personal knowledge of the facts set forth below and, if called as a witness, would testify competently that all statements are true and that all statements made on information and belief are believed to be true.

3. I conceived of the subject matter of the above-titled application at least as early as February 18, 1999, the filing date of the O'Hara patent (U.S. Patent No. 6,231,547).

4. Exhibit A shows all of the elements of claim 23 including a medical article comprising a multi-axis rotationally molded shell defining an interior cavity and said shell being formed of at least one layer of a polymer material.

5. As such, I have conceived of the subject matter of the above titled application prior to the effective dates of the O'Hara patent.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "David Schuessler", written over a horizontal line.

Dated: March 28, 2005

David Schuessler

TITLE ROTATIONAL MOLDED SHELLS

Project No. \_\_\_\_\_  
Book No. 6280

From Page No. MA

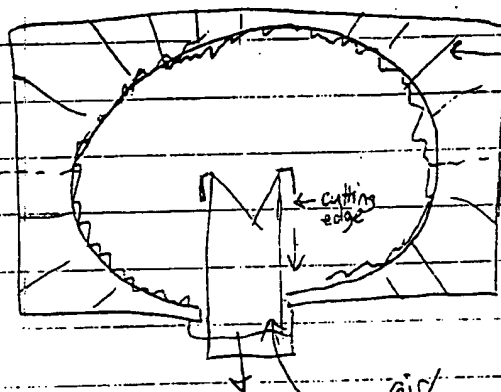
THIS NOTEBOOK IS TO CHRONICLE THE  
CONCEPTION AND DEVELOPMENT OF THE PROCESS  
TO ROTATIONALLY MOLD OR CAST BREAST IMPLANT  
SHELLS AND THE APPLICATION OF VARIOUS  
ROTATIONAL CASTING TECHNIQUES TO MAKE  
VARIOUS PROCESS AND PRODUCT IMPROVEMENTS.

From Page No. L

REDACTED

## Rotationally molded shell

Fit with predetermined wt. or vol. of dispersion to get consistent texture,  
high yields, uniform + known shell thickness. Cure while rotating on at  
least two axis in an oven



to strip: under vacuum

or use a section tip  
device to pull cured shell  
from mold

air solvent vent - removable to get shell out

End up with shell with normal  
patch hole.

How to make it patchless/seamless?

What type of rotational system?

Material would be viscous enough to coat the inner surface but not be dripping  
through the middle of the mold so air vent insert should stay relatively clean

Could even cure the gel in the mold with the shell if using just a patch vent  
(but then would have mold no way to get product out.

REDACTED

TITLE

From Pa

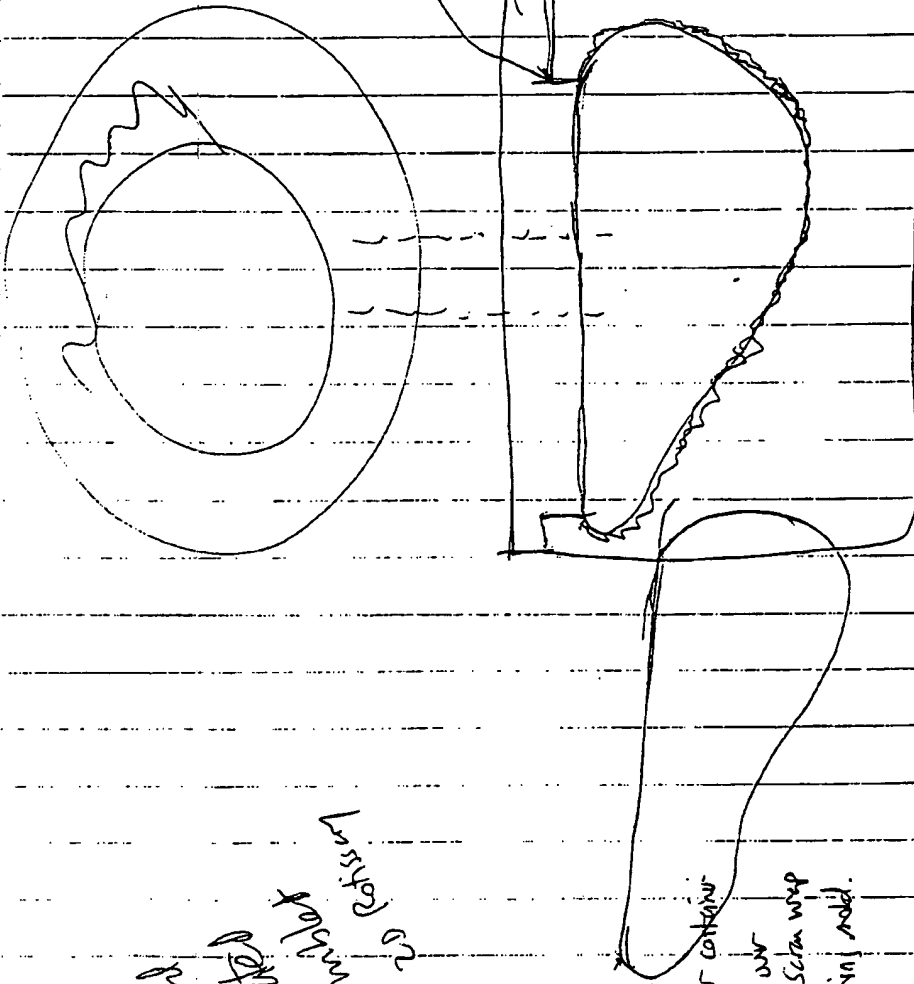
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Can it be patchless too.

~~REDACTED~~

RTV or other coating material - so

Qelbin?



Need  
to test  
the  
coating  
material

Suspend mandrel or implant over container  
Pour RTV all around up to 3/4 way  
radius. Lay a piece of Screen wrap  
to separate mold. Finish pouring mold.  
Let cure.

(Coil make mold out of RTV  
+ use an existing implant (or mandrel) to mold it  
The implant would give me the texture)

Per  
*[Signature]*

Witness

*[Signature]*

TITLE

RM SHELLS

Project No.

Book No. 62

From Page No. 6

REDACTED

STATUS REPORT p. 2

David Schuessler

5. MOULAGE KIT DOCUMENTATION

No change since last report.

--Met again with Doc. Services on 1/26. They are trying to work out non-technical issues. Their efforts will determine when this DCR gets done.

6. MAGNA-SITE IMPROVEMENT/REDESIGN

--No activity since last report. Still have yet to review PFR complaint files in the IS system myself.

7. FDA QUESTIONS/PMA/ABSTRACTS

--Done!? Not quite. Was asked this week to review a rewrite by RA for one of my Sept. '97 answers to the Saline PMA FDA questions.

8. TITANIUM REMOTE NEEDLE GUARD REPLACEMENT-3 PARTS

--This has been taken off the active interest list. However I believe this project could be completed without a lot of engineering effort.

9. PRODUCT "PERFORMANCE SPECIFICATION" DEVELOPMENT

--As we discussed, I am putting together an outline with an example product for our review and eventual presentation to Management.

OTHER PROJECTS

Rotational Molded Shells: I am investigating this alternative to shell/implant production.

Silence Patch Bond: Supporting Catherine Goudet in her efforts to improve the bond strength. I am coordinating the alteration of validation mandrels to add a sandblasted patch area for initial testing and have had made the necessary tooling/fixtures for production.

Mandrel Rod/Stem Redesign: Have designed a modified mandrel hole with a stem and a quick release mandrel rod. Objectives are to obtain better dispersion flow, eliminate rod bubbles, eliminate mandrel inserts, and save labor in threading mandrel rods in and out. Am having a demonstration sample made using a 163 prototype mandrel.

Mandrel Measurement Capability Study: I believe a flat ring on the bottom of the mandrel would help in projection measurement consistency. I am pursuing such a modification along with the 163 mandrel prototypes (Included in mandrel rod/stem redesign.)

To Page No. 7

W

REDACTED

TITLE

RM SHELLS

From Page No. 8

REDACTED

STATUS REPORT p. 2

David Schuessler

5. MOULAGE KIT DOCUMENTATION

- Nearly all documents in finished form. Performing dry run now.
- Scheduled for CCB week of May 25.

6. MAGNA-SITE IMPROVEMENT/REDESIGN

- No activity since last report. Still have yet to review PFR complaint files in the IS system myself.

7. FDA QUESTIONS/PMA/ABSTRACTS

- No activity since last report.

8. TITANIUM REMOTE NEEDLE GUARD REPLACEMENT--3 PARTS

- This has been taken off the active interest list. However I believe this project could be completed without a lot of engineering effort.

9. PRODUCT "PERFORMANCE SPECIFICATION" DEVELOPMENT

- Presentation to Senior Staff scheduled for Mon. 5/18.

10. ROTATIONALLY MOLDED SHELLS

- Have made a couple of crude trial runs. I like the possibilities.

11. MANDREL ROD/STEM REDESIGN

- Have designed a modified mandrel hole with a stem and a quick release mandrel rod. Objectives are to obtain better dispersion flow, eliminate rod bubbles, eliminate mandrel inserts, and save labor in threading mandrel rods in and out.
- Am having a demonstration samples made using a 163 prototype mandrel. Other mandrel features are being incorporated for presentation to Tech. Review probably 5/27.

No. 10

REDACTED

TITLE

DM 517.0

Project No.

Book No. 6280

11

REDACTED

Shell was not <sup>fully</sup> covered - Very tacky - Inhibited?

Should probably use something besides wax. But seemed to get full wax casting. Salt was very clumped. Should put hot salt on cold wax or not so hot of salt. CSR was not fully covered. Shouldn't put it in too hot a mold.

## STATUS REPORT p. 2

David Schuessler

5. MOULAGE KIT DOCUMENTATION

-I think its finally done. Should be to CCB next week.

6. MAGNA-SITE IMPROVEMENT/REDESIGN

(NO CHANGE SINCE LAST REPORT).

-Still have yet to review PFR complaint files in the IS system myself.

7. FDA QUESTIONS/PMA/ABSTRACTS

-Have been asked to review and revise my saline PMA questions two more times.

8. TITANIUM REMOTE NEEDLE GUARD REPLACEMENT--3 PARTS

(NO CHANGE SINCE LAST REPORT).

-This has been taken off the active interest list. However I believe this project could be completed without a lot of engineering effort.

9. PRODUCT "DEVICE SPECIFICATION" DEVELOPMENT

-Have outlined project, selected panel members, and am scheduling orientation meeting for week of June 8. First phase to be done by 8/31.

10. ROTATIONALLY MOLDED SHELLS

-Made a couple more trial castings. This will work! Researching prototyping equipment and mold materials. Should have a demonstration sample of a shell next week.

11. MANDREL ROD/STEM REDESIGN

AWAITING NEXT TECH REVIEW (6/10?) FOR PRESENTATION

(SEE ATTACHED FOR DETAILS)

-Have designed a modified mandrel hole with a stem and a quick release mandrel rod. Objectives are to obtain better dispersion flow, eliminate rod bubbles, eliminate mandrel inserts, and save labor in threading mandrel rods in and out.

-Am having a demonstration samples made using a 163 prototype mandrel. Other mandrel features are being incorporated for presentation to Tech. Review.

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